

JAN 27 1997

K 965096

EXHIBIT 15

Summary of Safety & Effectiveness

This device, the *Fluoroview™ Series Fluoroscopic Tables* (Model 9680) and the *Time Table C-Arm Stretcher, Model 9670* is designed for clinical applications such as: to support a patient and facilitate a diagnostic procedure employing some imaging technique or to position a patient for various treatments in clinics or hospitals. This device is used by a physician or a health care professional; this device is not operated by a patient. This is a Class II device. As such this device has a Classification name as: Mobile Fluoroscopic Tilting Table, as described in 21 CFR Part 892.11980. *U.S. Imaging Tables, Incorporated* has determined this device is substantially equivalent to a predicate medical device which is currently in commerce and is identified as: Deluxe "C" Arm Stretcher, Model 056-004, and is manufactured by Biodex Medical Systems, Inc. of Shirley New York.

A determination of substantial equivalence is based upon the following:

1. This device offers mechanical support and adjustment to suspend and position a patient into various arrangements where various parts of the patient would be accessible to an imaging system.
2. This device uses conventional design, construction and those materials commonly found in most similar Tables. This device uses conventional design, construction and those materials similar to the predicate, substantially equivalent device {except where this device is suited to a more general purpose design}.
3. This device has benefited from design, development, testing and production procedures that conform to Good Manufacturing Procedures.
4. This device has performance characteristics substantially equivalent to its predicate device {which includes differences to facilitate the various clinical applications for which it is intended}.
5. This device is safe and effective for the application for which it is intended and has been tested to confirm its safety and effectiveness.

U.S. Imaging Tables, Incorporated continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this device.

CERTIFICATION:

I hereby certify that this **Summary of Safety and Effectiveness** applies for the above indicated device.

Date

11/14/96

Signed by

Mr. Ronald Denezzo
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